

## INFORMATION DISCLOSURE STATEMENT

Applicant : Sir

Sircar et al.

App. No

10/661,139

Filed

September 12, 2003

For

PHENYL-INDOLE COMPOUNDS

FOR MODULATING IgE AND

INHIBITING CELLULAR

**PROLIFERATION** 

Examiner

Shameem, Golam M

Art Unit

1626

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application is a PTO/SB/08 Equivalent listing 98 references to be considered by the Examiner. Also enclosed are enclosed foreign patent references and/or non-patent literature as listed on the Information Disclosure Statement.

References EP 0 694 535, WO 09/56761, WO 00/6192, WO 00/9384, WO 00/8206, WO 00/32579, WO 00/4878, WO 01/2169, WO 01/4342, WO 02/72539 and WO 02/72574 are the PCT or European equivalents of the references cited by the Chilean Patent Office in the Chilean counterpart of a related application. These references are Chilean applications, and since they are not readily available, and not in English, their PCT, European or U.S. application/patent equivalents are submitted instead. For those PCT or European applications equivalents that are not in English, no U.S. patent or application equivalents are available. However, English abstracts are available in these applications. Applicants will have the non-English applications translated upon request. Reference CL 1693-2000 is also a Chilean application cited in the Chilean Search Report; however we have not been able to identify its counterpart application(s) based on the priority information provided by our foreign associate in Chile. The Chilean references and their corresponding PCT, European or U.S. applications/patents are provided herein.

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10/661,139

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Docket No. AVANIR.111A Customer No. 20,995

Chilean Application	PCT/EU/US Equivalents
CL 2666-1999	WO 00 29384
CL 2505-1999	WO 00 26192
CL 631-1995	EP 0 694 535
CL 2512-1998	WO 98 47890
CL 1119-2000	WO 00 68206
CL 2771-1999	WO 00 32579 (German)
CL 969-2000	WO 00 64878 (German)
CL 2184-2000	WO 01 12169
CL 1286-1998	WO 98 56761 (German)
CL 2215-2000	WO 01 14342 (German)
CL 457-2002	WO 02 72539 (German)
CL 467-2002	WO 02 72574
CL 148-1996	US 5,935,983
CL 1693-2000	Not available

Cite numbers 74-80 on the PTO SB/08 identify several co-pending applications filed by Applicant. Applicant directs the Examiner to these applications to consider whether the subject matter claimed, now or as may be amended in the future, as well as the associated prosecution history, now or in the future, may be relevant to the patentability of the present application (e.g., for reasons of obviousness-type double patenting). Applicant believes that the Examiner has access to the applications and associated file histories through the Patent Office (e.g., the IFW system). Accordingly, Applicant has not provided copies of these applications or their associated file histories, but would be happy to do so, now or in the future, should the Examiner so request.

This Information Disclosure Statement is being filed before the mailing date of a final action and before the mailing of a Notice of Allowance. This Statement is accompanied by the fees set forth in 37 C.F.R. § 1.17(p). The Commissioner is hereby authorized to charge any additional fees which may be required or to credit any overpayment to Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated:

Bv:

Mark R. Benedict

Registration No. 44,531 Attorney of Record

Customer No. 20,995

(949) 760-0404

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Q,		PTO/SB/08 Equivalent
oct 0.2 1000 w	Application No.	10/661,139
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TEMENT BY APPLICANT	First Named Inventor	Sircar et al.
	Art Unit	1626
(Multiple sheets used when necessary)	Examiner	Shameem, Golam M.
SHEET 1 OF 5	Attorney Docket No.	AVANIR.111A

			U.S. PATENT	DOCUMENTS	
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1.	US 4,582,837	04-15-1986	Hauel et al.	
	2.	US 4,696,931	09-29-1987	Hauel et al.	
	3.	US 5,017,467	05-01-1991	Masukawa et al.	
	4.	US 5,124,336	06-23-1992	Bru-Magniez, et al.	
	5.	US 5,322,847	06-21-1994	Marfat et al.	
	6.	US 5,380,865	01-10-1995	Cramp et al.	
	7.	US 5,712,392	01-27-1998	Thurkauf, et al.	
	8.	US 5,821,258	10-13-1998	Matsunanaga, et al.	
	9.	US 5,935,983	08-10-1999	Muller-Gliemann et al	
	10.	US 6,093,728	07-25-2000	McMahon et al.	
	11.	US 6,100,283	08-08-2000	Griffin, et al.	
	12.	US 6,100,282	08-08-2000	Alig, et al.	
	13.	US 6,153,631 A	11-28-2000	Petrie et al.	
	14.	US 6,271,390 B1	08-07-2001	Sircar et al.	
	15.	US 6,271,249	08-07-2001	Romine, et al.	
	16.	US 6,288,101	09-11-2001	Glennon	
	17.	US 6,303,645 B1	10-16-2001	Sircar et al.	
•	18.	US 2002/0010343	01-24-2002	Sircar et al.	
	19.	US 6,369,091 B1	04-09-2002	Sircar et al.	
	20.	US 6,387,938 B1	05-14-2002	Mizuguchi et al.	
	21.	US 6,451,829	09-17-2002	Sircar et al.	
	22.	US 2002/0132808	09-19-2002	Sircar et al.	
	23.	US 2003/0004203	01-02-2003	Sircar et al.	
	24.	US 6,537,994	03-25-2003	Ashwell et al.	
	25.	US 2003/0100582	05-29-2003	Sircar et al.	
	26.	US 2003/0100582	05-29-2003	Sircar et al.	
	27.	US 2004/0116466	06-17-2004	Sircar et al.	
	28.	US 6,759,425	07-06-2004	Sircar et al.	
-	29.	US 2004/0214821	10-28-2004	Sircar et al.	

Date Considered

T<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.

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	30.	US 2004/0229927	11-18-2004	Sircar et al.	
	31.	US 2005/0075343	04-07-2005	Sircar et al.	
	32.	US 6,911,462	06-28-2005	Sircar et al.	
	33.	US 6,919,366	07-19-2005	Sircar et al.	
	34.	US 2005/0197375	09-08-2005	Sircar et al.	
	35.	US 2005/0256179	11-17-2005	Sircar et al.	
	36.	US 2005/0277686	12-15-2005	Sircar et al.	

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Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T <sup>1</sup>
	37.	EP 0 221 146 A1	05-13-1987	Ryskamp		Abstract
	38.	EP 0 221 346 A1	05-13-1987	Conner et al.		
	39.	EP 0 232 199 A2	08-12-1987	Shroot et al.		Abstract
	40.	EP 0 415 886 A2	08-22-1990	Peter Herold		Abstract
	41.	EP 0 353 606 A2	02-07-1990	Nakayama et al.		
	42.	EP 0 385 850 A2	09-05-1990	Bru-Magniez et al.		Abstract
	43.	EP 0 469 477 A1	02-05-1992	O'Donnell et al.		
	44.	EP 0 497 564 A1	08-05-1992	Ashton et al.		
	45.	EP 0 694 535 A1	01-31-1996	Bruns et al.		<u> </u>
	46.	EP 0 700 906 A1	03-13-1996	Watson et al.		
	47.	EP 0 719 765 A2	07-03-1996	Matsunaga et al.		
	48.	EP 1 077 700 A1	02-28-2001	Sircar et al.		
	49.	EP 1 125 936 A2	08-22-2001	Goldstein et al.		
	50.	EP 1 123 295	08-16-2001	Harris et al.		
	51.	WO 89 06975	08-10-1989	Coffman et al.		-
	52.	WO 90 09989	09-07-1990	Makovek et al.		
- · · · · ·	53.	WO 93 25517	12-23-1993	Beeley et al.		

Examiner	Signature
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Date Considered

<sup>\*</sup>Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.

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	54.	WO 98 17267	04-30-1998	Orme et al.		
	55.	WO 98 47890	10-29-1998	Carter et al.		
	56.	WO 09 856761	12-17-1998	Drach et al.		
	57.	WO 99 61013 A1	12-02-1999	Sircar et al.		
	58.	WO 99 61019 A1	12-02-1999	Sircar et al.		
·	59.	WO 99 61020 A1	12-02-1999	Sircar et al.		
	60.	WO 00 26192 A1	05-11-2000	Lubisch et al.		
	61.	WO 00 29384 A1	05-25-2000	Lubisch et al.		
	62.	WO 00 68206 A1	11-16-2000	Lubisch et al.		
	63.	WO 00 32579 A1	06-08-2000	Lubisch et al.		
	64.	WO 00 64878 A1	11-02-2000	Lubisch et al.		
	65.	WO 01 12169 A2	02-22-2001	Camden		
	66.	WO 01 14342 A1	03-01-2001	Anderskewitz et al.		
	67.	WO 01 72737 A1	10-04-2001	Harling et al.		
	68.	WO 02 072539 A1	09-19-2002	Haning et al.		
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	70.	WO 02 72090	09-19-2002	Sircar et al.		Abstract
	71.	SU 1316559 (Russia)	06-21-1983	Khauel et al.		Abstract of U.S. Equivalent
	72.	JP 06 263993-A	09-01-1994	Tanaka et al.		Abstract
	73.	CL 1693-2000	2000	Chile		Abstract not Available

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
	74.	Related pending U.S. Patent Application No. 10/661,296, filed September 12, 2003. Title: Phenyl-Aza-Benzimidazole Compounds for Modulating IgE and Inhibiting Cellular Proliferation. Inventors: Jagadish C. Sircar et al.	
	75.	Related pending U.S. Patent Application No. 10/795,006, filed March 5, 2004. Title: Benzimidazole Compounds for Modulating IgE and Inhibiting Cellular Proliferation. Inventors: Jagadish C. Sircar et al.	

Examiner Signature	Date Considered

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	76.	Related pending U.S. Patent Application No. 10/821,667, filed April 9, 2004. Title: Imidazole Derivatives for Treatment of Allergic and Hyperproliferative Disorders. Inventors: Jagadish C. Sircar et al.		
	77.	Related pending U.S. Patent Application No. 10/915,722, filed August 9, 2004. Title: Selective Pharmacologic Inhibition of Protein Trafficking and Related Methods of Treating Human Diseases. Inventors: Jagadish C. Sircar et al.		
	78.	Related pending U.S. Patent Application No. 10/508,968, filed September 24, 2004. Title: Use of Benzimidazole Analogs in the Treatment of Cell Proliferation. Inventors: Jagadish C. Sircar et al.		
	79.	Related pending U.S. Patent Application No. 10/951,515, filed September 28, 2004. Title: Benzimidazole Derivatives as Modulators of IgE. Inventors: Jagadish C. Sircar et al.		
	80.	Related pending U.S. Patent Application No. 11/168,711, filed June 28, 2005. Title: Benzimidazole Compounds for Regulating IgE. Inventors: Jagadish C. Sircar et al.		
	81.	Manecke et al., Über Polyamide mit 2,4-Imidazolidiyl-Bausteinen, Die Makromolekulare Chemie 176, pgs. 3551-3563 (1975), 4/29/1975, Institut für Organische Chemie der Freien Universität Berline, D-1 Berlin 33		
	82.	Cheney B V, et al., "Structure-activity Correlations for a Series of Antiallergy Agents. 3. Development of a Quantitative Model," Journal of Medicinal Chemistry, vol. 26, No. 5, 1983, pp. 726-737.		
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	85.	Database Crossifre Beilstein 'Online!, Beilstein Institut zur Forderung der Chemischen Wissenchaften, Frankfurt am Main, DE; Beilstein Registry Number 563073 & Khim. Farm. ZH., Vol. 22, No. 6, 1988, pgs. 697-699.		
	86.	Karag'ozov S, "Synthesis of N-acyl Derivatives of 6-amio-1-4-benzodioXane," STN International, Vol. 39, No. 1989 pp. 5-8, Abstract only.		
	87.	Masukawa et al., Calplus 111:31259 (EP 304856, 3/1/89)		
	88.	Denny W A et al., "Potential antitumor agents. 59. Structure-activity relationships for 2-phenylbenzimidazole-4-carboXamides, a new class of "minimal" DNA-intercalating agents which may not act via topoisomerase II", Journal of Medicinal Chemistry, Vol. 33, No. 2, February 1990, pgs. 814-819.		
	89.	Yildir I, "Synthesis of 32-(subtitutephenyl) Benzimidazole Derivatives and their Sedative Activity: Structure-activity Relationships," Journal FaX. Pharm. Gazi Uni., Vol. 7, No. 2, 1990, pp. 111-114		
	90.	Timothy F. Gallagher, et al., "2,4,5-Triarylimidazole Inhibitors of IL-1 Biosynthesis," Bioorganic & Medicinal Chemistry Letters, Vol. 5, No. 11, pp. 1171-1176, 1995		

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	91.	Ashton et al., "New Low-Density Lipoprotein Receptor Upregulators Acting via a Novel Mechanism," Journal of Medicinal Chemistry, Vol. 39, Jan. 1, 1996, pp. 3343-3356.			
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	93.	Kreimeyer A et al., "Suramin analogues with a 2-phenylbenzimidazole moiety as partyial structure; potential anti HIV-and angiostic drugs, 2: Sulfanilic acid, benzendisulfonic, and naphthalenetrisulfonic acid analogues" Archi Der Pharmazie, Vol. 331, no. 3, March 1998, pgs. 97-103.			
	94.	Japanese Application No. 10273013, entitled Antagonist for Gonadotrophic Hormone-Releasing Hormone, filed on September 28, 1998, English abstract only.			
	95.	Database Caplus 'Online! Chemical Abstracts Service, Columbus, Ohio, US; Databse accession no. 2000:214835 & JP 2000 095767 (Takeda Chemical Industries, Ltd.), April 4, 2000.			
	96.	White A W et al., "Resistance-modifying agents. 9. Synthesis and biological properties of benzimidazole inhibitors of the DNA repair enzyme poly(ADP-ribose) polymerase", Journal of Medicinal Chemistry, Vol. 43, No. 2, November 2, 2000, pgs. 4084-4097.			
	97.	Chilean Office Action with Search Report for the Chilean counterpart of the U.S. Patent Application No. 10/795,006.			
	98.	Chemical structure database (CA, CAPLUS, CHEMCATS) search results for bis-5,4'-dibenzanilide-2- phenylbenzimidazole (Registry Number 98806-53-2)			

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Examiner Signature Date Considered